K110579

OCT - 6 2011

Admin 3.0

510(k) Summary (Summary of Safety and Effectiveness)

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Applicant Name

Darla Abano, Senior Regulatory Affairs Administrator
Regulatory Affairs
Abbott Laboratories Diagnostics Division
Dept 9V6, AP5N-2
100 Abbott Park Road
Abbott Park, IL 60064

Device Name

Reagents
Classification Name: Vitamin B12 test system
Trade Name: ARCHITECT B12
Common Name: B12
Governing Regulation: 862.1810
Device Classification: Class II
Classification Panel: Clinical Chemistry
Product Code: CDD

Calibrators
Classification Name: Calibrator
Trade Name: ARCHITECT B12 Calibrators (A-F)
Common Name: Calibrator
Governing Regulation: 862.1150
Device Classification: Class II
Classification Panel: Clinical Chemistry
Product Code: JIT

Controls
Classification Name: Quality Control Material (assayed and unassayed)
Trade Name: ARCHITECT B12 Controls (Low, Medium, and High)
Common Name: Control
Governing Regulation: 862.1660
Device Classification: Class I
Classification Panel: Clinical Chemistry
Product Code: JJX

Legally Marketed Device to Which Equivalence is Claimed

Roche Elecsys Vitamin B12 Immunoassay (K060755)

Intended Use of Device

The ARCHITECT B12 assay is a chemiluminescent microparticle Intrinsic Factor assay for the quantitative determination of vitamin B12 in human serum on the ARCHITECT *i* System.

Description of Device

Reagent Kit

The ARCHITECT B12 assay is a two-step assay with an automated sample pretreatment, for determining the presence of B12 in human serum using chemiluminescent microparticle immunoassay (CMIA) technology with flexible assay protocols, referred to as Chemiflex.

Sample and Pre-Treatment Reagent 1, Pre-Treatment Reagent 2, and Pre-Treatment Reagent 3 are combined. An aliquot of the pre-treated sample is aspirated and transferred into a new reactions vessel (RV). The pre-treated sample, assay diluent, and intrinsic factor coated paramagnetic microparticles are combined. B12 present in the sample binds to the intrinsic factor coated microparticles. After washing, B12 acridinium-labeled conjugate is added in the second step. Pre-Trigger and Trigger Solutions are then added to the reaction mixture; the resulting chemiluminescent reaction is measured as relative light units (RLUs). An inverse relationship exists between the amount of B12 in the sample and the RLUs detected by the ARCHITECT *i* System optics.

Calibrators

The ARCHITECT B12 Calibrators are used to calibrate the ARCHITECT i System when the system is used for the quantitative determination of vitamin B12 in human serum using the ARCHITECT B12 Reagent Kit.

Controls

The ARCHITECT B12 Controls are used for the estimation of test precision and the detection of systematic analytical deviations of the ARCHITECT i System when used for the quantitative determination of vitamin B12 in human serum when using the ARCHITECT B12 Reagent Kit.

Comparison of Technological Characteristics

The ARCHITECT B12 assay utilizes chemiluminescent microparticle immunoassay (CMIA) technology for the quantitative determination of vitamin B12 in human serum. The Roche Elecsys E170 Vitamin B12 assay utilizes technology for the quantitative determination of vitamin B12 in human serum and plasma on the E170 System.

Summary of Nonclinical Performance

The data presented in the pre-market notification demonstrate that the ARCHITECT B12 assay performs substantially equivalent to the predicate device, the Roche Elecsys E170 Vitamin B12 assay (K060755). Equivalence was demonstrated using the current commercially available Roche Elecsys E170 Vitamin B12 reagents with 172 patient samples covering the range of 83 pg/mL to 2000 pg/mL. The data presented in the premarket notification provide a reasonable assurance that the ARCHITECT B12 assay is safe and effective for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Abbott Laboratories
c/o Darla Abaño
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100 Abbott Park Road
Abbott Park, IL 60064

OCT - 6 2011

Re: k110579
Trade/Device Name: ARCHITECT B12 Reagent Kit, ARCHITECT B12 Controls, ARCHITECT B12 Calibrators
Regulation Number: 21 CFR 862.1810
Regulation Name: Vitamin B12 Test System
Regulatory Class: Class II
Product Code: CDD, JIT, JJX
Dated: August 30, 2011
Received: August 31, 2011

Dear Ms. Abaño:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k110579

Device Name: ARCHITECT B12 Reagent Kit, ARCHITECT B12 Controls, ARCHITECT B12 Calibrators

Indications for Use

The ARCHITECT B12 assay is a chemiluminescent microparticle Intrinsic Factor assay for the quantitative determination of vitamin B12 in human serum on the ARCHITECT *i* System. Measurements obtained by this device are used in the diagnosis and treatment of anemias of gastrointestinal malabsorption.

The ARCHITECT B12 Controls are used for the estimation of test precision and the detection of systematic analytical deviations of the ARCHITECT *i* System when used for the quantitative determination of vitamin B12 in human serum when using the ARCHITECT B12 Reagent Kit.

The ARCHITECT B12 Calibrators are used to calibrate the ARCHITECT *i* System when the system is used for the quantitative determination of vitamin B12 in human serum using the ARCHITECT B12 Reagent Kit.

Prescription Use _X_ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) k110579